



Office of the Secretary

Declaration Amendment

ACTION: Notice of amendment.

SUMMARY: The Secretary is amending the Declaration issued in the Federal Register of October 10, 2008, as amended April 26, 2009; December 17, 2008; February 29, 2012; and as amended and republished January 1, 2016, pursuant to section 319F-3 of the Public Health Service Act to extend the effective time period of the Republished Declaration, as amended.

DATES: This amendment of the January 1, 2016 Republished Declaration is effective January 1, 2023.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Administration for Strategic Preparedness and Response, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; 202-260-0365, paige.ezernack@hhs.gov.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (Covered Countermeasures), except for claims that meet the PREP Act's definition of willful misconduct. The Secretary may, through publication in the Federal Register, amend any portion of a Declaration. Using this authority, the Secretary issued several Declarations for countermeasures against pandemic influenza: (1) An October 10, 2008, Declaration covering the neuraminidase class of antivirals Oseltamivir Phosphate (e.g., Tamiflu) and Zanamivir (e.g. Relenza) (hereinafter, “antivirals Declaration”); (2) a December 17, 2008, Declaration covering pandemic influenza diagnostics, personal respiratory protection devices, and respiratory support devices (hereinafter “diagnostics and other devices Declaration”); (3) a February 29, 2012, amended Declaration covering pandemic

influenza vaccines (hereinafter, “vaccines Declaration”); and (4) a January 1, 2016, amendment republishing the prior Declarations as a single Declaration in its entirety, as amended (hereinafter, “Declaration”); and is amending the Republished Declaration.

The PREP Act was enacted on December 30, 2005, as Public Law 109-148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding Section 319F-3, which addresses liability immunity, and Section 319F-4, which creates a compensation program. These sections are codified in the U.S. Code as 42 U.S.C. 247d-6d and 42 U.S.C. 247d-6e, respectively. Section 319F-3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113-5, enacted on March 13, 2013, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116-136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

This Secretary is now amending the Republished Declaration to extend the time period for which liability immunity is in effect for all of the Covered Countermeasures to December 31, 2027.

Pandemic influenza A viruses and influenza A viruses with pandemic potential continue to pose a public health threat to the United States. These Influenza A viruses have the potential to become highly transmissible in the U.S. population, causing significant morbidity and mortality. PREP Act coverage of Influenza A countermeasures is critical to enable continuity of ongoing programs for development of critical diagnostics, vaccines, and therapeutics, and accomplish national pandemic preparedness goals. In addition, PREP Act declaration renewal is essential to support uninterrupted readiness and access to stockpiled pre-pandemic influenza vaccines to mitigate an emerging pandemic.

Unless otherwise noted, all statutory citations below are to the U.S. Code.

Republished Declaration

Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Pandemic Influenza Countermeasures

This Declaration amends the October 17, 2008, Declaration under the Public Readiness and Emergency Preparedness Act, as amended on April 26, 2009; the December 17, 2008, Declaration under the Public Readiness and Emergency Preparedness Act; the February 29, 2012, Declaration under the Public Readiness and Emergency Preparedness Act; and the January 1, 2016 Republished Declaration under the Public Readiness and Emergency Preparedness Act. To the extent any term of the prior Declarations is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.

I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

42 U.S.C. 247d-6d(b)(1)

I have determined there is a credible risk that pandemic influenza A viruses and influenza A viruses with pandemic potential could cause an influenza pandemic with resulting disease that may constitute a public health emergency.

II. Factors Considered

42 U.S.C. 247d-6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d-6d(b)(1)

I recommend, under the conditions stated in this Declaration, the manufacture, testing, development, distribution, administration, or use of the Covered Countermeasures.

IV. Liability Immunity

42 U.S.C. 247d-6d(a), 247d-6d(b)(1)

Liability immunity as prescribed in the Public Readiness and Emergency Preparedness (PREP) Act and conditions stated in this Declaration is in effect for the Recommended Activities described in Section III.

V. Covered Persons

42 U.S.C. 247d-6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are manufacturers, distributors, program planners, “qualified persons,” and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I have determined that the following additional persons are qualified persons: (a)

Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents,

employees, contractors and volunteers, following a declaration of an emergency; (b) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is

otherwise authorized to perform an activity under an Emergency Use Authorization in

accordance with section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act, and; (c) Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.

VI. Covered Countermeasures

42 U.S.C. 247d-6b(c)(1)(B), 42 U.S.C. 247d-6d(i)(1) and (7)

Covered Countermeasures are any antiviral, any other drug, any biological product, any diagnostic, any respiratory protective device, any other device, or any vaccine used against pandemic influenza A viruses and influenza A viruses with pandemic potential, all components and constituent materials of vaccines, and all devices and their constituent components used in the administration of vaccines, except that vaccines against influenza A and their associated

components, constituent materials and devices covered under the National Vaccine Injury Compensation Program are not Covered Countermeasures.

Covered Countermeasures must be “qualified pandemic or epidemic products,” or “security countermeasures,” or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

VII. Limitations on Distribution

42 U.S.C. 247d-6d(a)(5) and (b)(2)(E)

I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to:

(a) Present or future Federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other Federal agreements, or activities directly conducted by the Federal Government;

or

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a declaration of an emergency.

i. The Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, state, or Federal boundary lines) or functional (e.g., law enforcement, public health) range or sphere of authority.

ii. A declaration of emergency means any declaration by any authorized local, regional, state, or Federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures, with the exception of a Federal Declaration in support of an Emergency Use Authorization under section 564 of the FD&C Act unless such Declaration specifies otherwise;

I have also determined that for governmental program planners only, liability immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from Federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d-6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is the threat of or actual human influenza that results from the infection of humans following exposure to pandemic influenza A viruses or influenza A viruses with pandemic potential.

Pandemic influenza A viruses and influenza A viruses with pandemic potential mean: Animal viruses and/or human influenza A viruses circulating in wild birds, domestic animals and/or humans that cause or have significant potential to cause sporadic or ongoing human infections, or historically have caused pandemics in humans, or have mutated to cause pandemics in humans, and for which the majority of the population is immunologically naive.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d-6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

X. Population

42 U.S.C. 247d-6d(a)(4), 247d-6d(b)(2)(C)

The populations of individuals include any individual who uses or is administered the Covered Countermeasures in accordance with this Declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered to this population, or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d-6d(a)(4), 247d-6d(b)(2)(D)

Liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in these geographic areas; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in these geographic areas, or the program planner or qualified person reasonably could have believed the recipient was in these geographic areas.

XII. Effective Time Period

42 U.S.C. 247d-6d(b)(2)(B)

For any Covered Countermeasure subsequently covered under the National Vaccine Injury Compensation Program, liability immunity under this Declaration expires immediately upon such coverage.

Liability immunity for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction extends through December 31, 2027, or until a Covered Countermeasure is covered under the National Vaccine Injury Compensation Program, as applicable, whichever occurs first.

Liability immunity for Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with a Declaration and lasts through (1) the final day the emergency Declaration is in effect; (2) December 31, 2027; or (3) until a Covered Countermeasure is covered under the National Vaccine Injury Compensation Program, as applicable, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d-6d(b)(3)(B) and (C)

I have determined that an additional twelve (12) months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take other appropriate actions to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the Strategic National Stockpile (SNS) during the effective period of this Declaration for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction are covered through the date of administration or use pursuant to a distribution or release from the SNS

XIV. Countermeasures Injury Compensation Program

42 U.S.C. 247d-6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a serious physical covered injury as the direct result of the administration or use of the Covered Countermeasures and/or benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical, and scientific evidence in order for the individual to be considered for compensation. The CICP is

administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at the toll-free number 1-855-266-2427 or <https://www.hrsa.gov/cicp/>.

XV. Amendments

42 U.S.C. 247d-6d(b)(4)

The October 10, 2008, Declaration Under the Public Readiness and Emergency Preparedness Act for pandemic influenza antivirals was first published on October 17, 2008, and amended effective April 26, 2009.

The December 17, 2008, Declaration Under the Public Readiness and Emergency Preparedness Act for diagnostics and other devices was first published on December 22, 2008.

The Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1 vaccines was first published on January 26, 2007. The Declaration was amended on November 30, 2007, to add H7 and H9 vaccines; amended on October 17, 2008, to add H2 and H6 vaccines; amended on June 15, 2009, to add 2009 H1N1 vaccines and republished in its entirety; amended on September 28, 2009, to provide targeted liability protections for pandemic countermeasures to enhance distribution and to add provisions consistent with other Declarations and republished in its entirety; amended on March 1, 2010, to revise the Covered Countermeasures to include countermeasures against pandemic influenza A viruses, extend the effective date and republished in its entirety; and amended on February 29, 2012, to extend the effective time period, reformat the Declaration, and republish the Declaration.

The January 1, 2016, Republished Declaration Under the Public Readiness and Emergency Preparedness Act amended all Declarations and amendments prior to the date of its publication in the Federal Register and republished the prior Declarations in the Federal Register as a single Declaration in its entirety, as amended.

This Declaration republishes the January 1, 2016 Declaration to extend the effect time period. Further amendments to this Declaration will be published in the Federal Register.

Authority: 42 U.S.C. 247d-6d.

Xavier Becerra,
Secretary of Health and Human Services.

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